

### REMARKS

Claims 1-5, 39-54, and 72-81 are pending in the current application. Of the above claims, 39-54 have been withdrawn from consideration as drawn to a method of practicing the invention. Therefore, claims 1-5 and 72-81 are currently pending in the present application and stand rejected.

The Examiner's acknowledgement of the Information Disclosure Statement submitted by applicant on March 10, 2003, which was not matched with the file before mailing the non-final rejection of March 24, 2003, and his subsequent consideration of the Information Disclosure Statement is greatly appreciated.

In response to paragraph 3 of the detailed action, the undersigned attorney for Applicant reaffirms that all of the claims were made by the currently named joint inventors.

The Examiner rejects claims 1-5 and 72-81 as being obvious under 35 U.S.C. §103(a) in view of the combination of the Bartels, et al. U.S. Patent No. 4,621,632 (hereinafter '632) when it is combined with the Danielle, et al. U.S. Patent No. 6,050,260 (hereinafter '260). The Examiner states "Bartels, et al. teaches all of the limitation of the claims except for explicitly reciting a humidity sensing means and a monitoring means connected to the humidity sensing means for monitoring the humidity of the gas and keeping it within a determined threshold. Danielle, et al. teaches a humidity sensing means and a monitoring means for monitoring the humidity of the gas and keeping it within a determined threshold. It would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the humidity device of Bartels to monitor humidity by a humidity sensing means, while keeping the humidity with a predetermined range or threshold for the well-known purpose of preventing a cavity that is normally moist from drying out thereby causing inflammation causing discomfort."

For the Examiner's *prima facie* case of obviousness to withstand scrutiny, three requirements must be met: (1) There must be some suggestion or motivation to combine the references (in this case, the '632 and '260 patents), and the suggestion may come from the references themselves or from the knowledge generally known in the art (MPEP §2143.01); (2) A reasonable expectation of success is required, and (3) the prior art reference, or references when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claim combination, and the reasonable expectation of success must both be found in the prior art, and not be based on Applicant's disclosure. "There are three possible sources for a motivation to combine the references: The nature of the problem to be solved, the teaching of the prior art, and the knowledge of persons of ordinary skill in the art." *In Re: Rouffet*, 47 USPQ 2d 1453, (CAFC 1998).

In order to understand why the *prima facie* case of obviousness must fail, an understanding of the differences in, and development of, thoracic surgery and laproscopic surgery is desirable. Residencies in thoracic surgery began around the 1940's. Student's in such residencies spend a very small time studying the peritoneum. Therefore, students in such residencies know of the peritoneum, but have no knowledge of problems which go on in the peritoneum. Student's in thoracic residencies would not know even know the peritoneal temperature or humidity at which peritoneal cells would not do well.

As will be shown to be important hereinafter, thoracic surgeons are not familiar with problems caused by needing to place a trocar into a confined space and then inflate the confined space. Instead, thoracic surgeons are familiar with lungs, and can introduce something into the lungs through an existing outside passageway of the body, i.e., the mouth.

In complete contrast to this, laproscopic residencies appeared in approximately 1970. Students of such a residency soon learn the problems which result from operating in a confined space, i.e., the peritoneum, as opposed to the problems which thoracic surgeons would be familiar with, i.e., the lungs are a warm moist environment and adding humidity to already humid air entering the lungs would make it only more relatively or less relatively moist.

However, laproscopic residents would learn that air is not a gas to be introduced into the abdomen. In fact, present day, government regulations say that air cannot be introduced into the abdomen because it supports combustion. It can be dangerous to the patients because of the fact that it supports combustion. Instead, laproscopic surgeons are familiar with using safe, dry, non-combustible gas such as carbon dioxide, nitric oxide, argon or helium. Therefore, the teaching of the prior art does not suggest the combination of references proposed by the Examiner.

Next, problems became evident in laproscopic surgery shortly after such surgery was invented. Hypothermia, shoulder pain and adhesions became familiar to the laproscopic surgeons. These problems persisted for approximately 20 years, with nobody arriving at a solution. It was not until Dr. Douglas Ott, one of the inventors in the present application, discovered what was happening. He discovered that the dry carbon dioxide, or other gasses, being used in laproscopic surgery was causing the problem. Because trocars were used to introduce carbon dioxide into the abdomen, and the major portion of the trocar was occupied by the surgical instruments being used, the gas was actually being introduced into the abdomen at a relatively high speed in the annular shaped cross-sectional area not occupied by the surgical instrument.

Further analysis by Dr. Ott drew the analogy that because of the high velocity of the gasses entering the peritoneum, something like “wind chill” was occurring. It was further determined that because of the “bone dry” nature of the gas supplied by insufflators, that heating and humidifying of the gas was needed. It was only after this analysis that the inventors arrived at the solution to the problems in the laproscopic field. The knowledge of humidifying air was known from the respiratory field for 25 years. There was a long felt need for the solution to the problems of hypothermia, shoulder pain, and adhesion, and if it would have been obvious from the respiratory field, i.e., Bartels, et al. and Danielle, et al., these problems would have been solved long before. Therefore, the *prima facie* case also fails for the reason that there is no motivation to combine the references based on the nature of the problem to be solved. The problem simply does not exist in the respiratory field. The ‘632 and ‘260 references both deal with respiratory devices. Respiratory devices deal with supplying already moist (not dry) air (not carbon dioxide) to the outside of the body to be inhaled through a naturally occurring opening in the body such as a nasal passages or the mouth.

Lastly, medical education today is so highly specialized that thoracic surgeons, who deal with problems associated with the lungs, would not be permitted to operate on organ in the abdomen. They would not know much about the peritoneum. Further, they would not know about the temperature at which peritoneal cells do not do well. Likewise, laproscopic surgeons would not be able to operate on the lungs. Laproscopic surgeons are dealing with hypothermia, shoulder pain, adhesions and other problem in the abdomen caused by the gas being either too cold or too dry. Thus, to a laproscopic surgeon, suggesting that the ‘632 or ‘260 could solve problems in their area of expertise, would be like comparing apples to oranges. Therefore, motivation does not come from the knowledge of those skilled in the art.

In addition to their being no motivation to combine, the references themselves, if not conflicting, and if combined for the sake of argument, would not teach every element of the claimed invention. The '260 patent to Danielle states as its purpose, to vary the pressure of gasses supplied by the apparatus so that the humidity of the gasses supplied to a patient are always at the maximum of the capability of the humidifier to humidify that airflow. In reality, Danielle, et al. does not even use a humidity sensor, but an algorithm or look up table, and simply turns up the speed of his fan as the heater plate temperature increases (column 4, lines 14-19).

However, Danielle says that any suitable humidity sensor could alternatively be used. (column 4, lines 23 –24). The substitution of a humidity sensor in Danielle would do nothing to achieve the purpose of Applicant to set off an alarm when the humidity falls below a certain level. Danielle is only interested in increasing the humidity to maximum. Even if Danielle had a humidity sensor, the most he would do is to turn up the fan speed as the humidity rises. Again, he would never need to know the actual humidity, much less, when it falls below a certain level.

Likewise, Bartels, et al. as stated at column 8, lines 51-65, is only interested in overheating and overhumidifying the air where it enters the flexible heating tube 36, and maintaining the temperature in the tube 36, through optional heater element 42, to prevent rain-out. Bartels does not even know what the humidity in his system is, as at column 9, lines 32-35, the patients breath after inspiration, in certain cases, could be very low in humidity, but that would be remedied in the next breath.

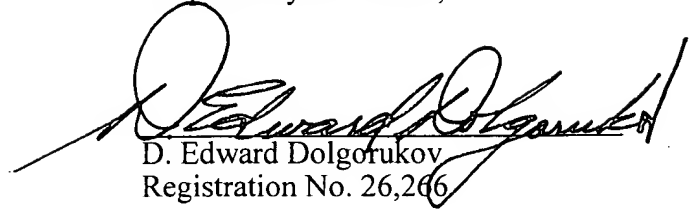
At paragraph 10, lines 20-25, the system does sound an alarm when either the proximal temperature sensed by thermistor 12, or the humidity chamber outlet temperature sensed by the thermistor 10, drops below a certain temperature. An alarm is sounded based on temperature not

relative humidity, and not relative humidity falling below a certain point, as is disclosed and claimed in the present invention. Thus, Danielle, et al. and Bartels et al. are interested in regulating temperature to keep humidity at a maximum level and not to sound an alarm when humidity falls below a certain level.

Further, “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious” *In Re: Ratti* 123 USPQ 2d 349 (CCPA 1959). It can be seen that to arrive at the invention of Applicant’s, not only would Bartels, et al. and Danielle, et al. need to be combined, but the whole principle of operation would need to be changed of both Danielle, et al. and Bartels, et al.; i.e., no longer operating to overhumidify air or to maximize the humidity in the air, but to monitor the humidity and indicate when it has fallen below a certain level. Court’s have reversed these type of rejections holding “the suggested combination of references would require a substantial reconstruction and redesign of the elements shown in the primary reference as well as the change in the basic principle under which the primary reference construction was designed to operate”. *In Re: Ratti* 123 USPQ 2d 349 (CCPA 1959).

Therefore, since there is no motivation to combine, no reasonable expectation of success and the prior art does not teach or suggest all of the claim limitations, it respectfully maintained that the claims, as amended, are allowable over the prior art cited by the Examiner. If for any reason the claim are not allowable over the prior art, a telephone conference with the Examiner is specifically requested to place this case in condition for allowance.

Respectfully submitted,



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